

REMARKS

This is a response to the non-final Office Action dated June 1, 2011. A petition for a one month extension of time is submitted with this response. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 3712036-00745. If such a withdrawal is made, please indicate the Attorney Docket No. 02-1818 on the account statement.

Claims 1-8, 12-16, 18-21, 31-33, 35-37, and 39-40 are currently pending. Claims 9-11, 17, 22-30, 34 and 38 were previously canceled without disclaimer. In the Office Action, Claims 1-8, 12-16, 18-21, 31-33, 35-37, and 39-40 are rejected under 35 U.S.C. §103(a). In response, Claims 1, 4-6, 12, 16, 31-33, 35-37 and 39 have been amended. The amendments do not add new matter. For at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

Claims 12, 16, 31-33, 35-37 and 39 have been amended to correct the spelling of "ingestible."

In the Office Action, Claims 1-8, 12-16, 18-21, 31-33, 35-37, and 39-40 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,380,252 to De Simone ("*De Simone*"), U.S. Patent No. 6,063,820 to Cavazza ("*Cavazza I*"), U.S. Patent No. 6,348,495 to Cavazza et al. ("*Cavazza II*"), U.S. Publication No. 2002/0077349 to Hamilton ("*Hamilton I*"), U.S. Publication No. 2003/0060503 to Hamilton ("*Hamilton II*"), U.S. Patent No. 6,503,506 to Germano ("*Germano*"), U.S. Publication No. 2001/0031774 to Kosbab ("*Kosbab*") and US Publication No. 2003/0224071 to Murad ("*Murad*"). Applicants respectfully traverse the rejection for at least the reasons set forth below.

Independent Claims 1 and 4-5 recite, in part, a method for the stimulation of the lipid metabolism in the skin of an animal or a human comprising administering an ingestible composition comprising L-carnitine, vitamin C, vitamin E, grape seed extract and cysteine. The amount of L-carnitine administered daily is from about 1 mg to about 1 g per kg of body weight and the amount of vitamin C administered daily is from about 0.025 mg to about 250 mg per kg of body weight.

Independent Claim 6 recites, in part, a method for making an ingestible composition for the stimulation of the lipid metabolism in the skin of an animal or a human being, comprising the step of using L-carnitine, vitamin C, vitamin E, grape seed extract and cysteine to make the

composition. The amount of L-carnitine administered daily is from about 1 mg to about 1 g per kg of body weight and the amount of vitamin C administered daily is from about 0.025 mg to about 250 mg per kg of body weight.

Independent Claim 18 recites, in part, an ingestible composition selected from the group consisting of a medicament, a food, a functional food, a nutritional complete pet or human food, and a dietary supplement comprising L-carnitine, vitamin C, vitamin E, grape seed extract and cysteine. The amount of L-carnitine administered daily is from about 1 mg to about 1 g per kg of body weight and the amount of vitamin C administered daily is from about 0.025 mg to about 250 mg per kg of body weight.

Conventional methods of improving skin involve the use of topical formulations that merely treat the symptoms of skin conditions, or ingestible compositions that contain rare and expensive starting materials of plant or animal origin. See, specification (WO 2005/074719), page 1, line 19-page 2, line 5. In contrast, the present claims provide an ingestible composition comprising L-carnitine, vitamin C, vitamin E, grape seed extract and cysteine and methods of administering or using the same. The claimed combination of ingredients surprisingly demonstrates a protective activity with respect to inflammatory skin diseases, helps to avoid dermatitis, and increases the lipid secretion in sebum. See, specification, page 5, lines 8-12; page 14, line 1-page 15, line 18; Table 1.

Applicants respectfully submit that one of ordinary skill in the art would have no reason to combine the teachings of *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II*, *Germano*, *Kosbab* and *Murad* to arrive at independent Claims 1, 4-6 and 18. The present claims are directed primarily to treatment of the skin and stimulation of lipid metabolism. The references cited by the Examiner, in contrast, are directed to different uses of certain ingredients from the claimed composition. They do not disclose methods for treating the skin or stimulating lipid metabolism in the skin according to the present claims.

De Simone is entirely directed to the use of L-acetylcarnitine to induce the production of IGF-1 and treat cytological disorders or diseases related to IGF-1 such as neuropathies of the optic and olfactory nerves, paralysis and osteoporosis. See, *De Simone*, Title; Abstract; column 1, lines 15-34; column 2, lines 44-49. *De Simone* is entirely unconcerned with treating skin disorders or stimulating the lipid metabolism in the skin to increase the lipid secretion in sebum and fails to even mention the terms "skin," "lipid metabolism" or "sebum."

Cavazza I is directed to a medical food for diabetics comprising γ -linolenic acid and an L-carnitine derivative. See, *Cavazza I*, Title; Abstract; column 2, lines 17-26. *Cavazza I* teaches that its medical food bypasses the enzyme blockade that results in the inadequate conversion of linoleic acid into γ -linolenic acid. See, *Cavazza I*, column 2, lines 17-26. *Cavazza II* is directed to the use of alkanoyl L-carnitine to treat inflammatory bowel diseases. See, *Cavazza II*, Title; Abstract; column 1, lines 11-20; column 2, lines 62-67; column 3, lines 1-7. *Cavazza I* and *Cavazza II* are entirely unconcerned with treating skin disorders or stimulating the lipid metabolism in the skin to increase the lipid secretion in sebum.

Hamilton I is directed to the administration of carnitine and lipid acid to promote healthy mitochondria and treat age-related vision impairment. See, *Hamilton I*, Title; Abstract; page 1, paragraph 2; pages 2-3, paragraph 23. *Hamilton II* is directed to nutritional supplements for mature pets comprising α -lipoic acid and carnitine. See, *Hamilton II*, Title; Abstract; page 1, paragraph 2. Indeed, *Hamilton II* merely discloses that lipoic acid can be used in compositions for improving the skin. At no place does *Hamilton I* or *Hamilton II* recognize the benefits obtained by administering the compositions of the present claims.

Germano is entirely directed to a nutritional supplement for treating chronic debilitating diseases such as HIV/AIDS comprising SOD, whey, glutamine, coenzyme Q10 and L-carnitine. See, *Germano*, Title; Abstract. As such, *Hamilton I*, *Hamilton II* and *Germano* are entirely unconcerned with treating skin disorders or stimulating the lipid metabolism in the skin.

Kosbab is entirely directed to compositions to ameliorate the disease symptoms and conditions associated with vascular and capillary disorders. The compositions may include antioxidants, neovascular regulators, promoters or cofactors involved in collagen synthesis, as well as vitamins and minerals to supplement deficiencies. See, *Kosbab*, Abstract; page 1, paragraph 2. Specifically, *Kosbab* is directed to tissue and cell damage due to oxidative stress and breakdown of collagen in tissues. See, *Kosbab*, page 1, paragraph 9. At best, *Kosbab* discloses the use of L-carnitine among a laundry list of other additives including, for example, butylated hydroxytoluene, ethoxiquin, bioflavins, catchins, angiogenesis regulators, fenugreek, and gymnemic acid, among many others. At no place in the disclosure does *Kosbab* recognize the benefits achieved when the ingredients of the present claims are combined in the presently claimed amounts. The Examiner asserts that *Kosbab* "does specifically state that L-carnitine may assist a subject with lipid metabolism problems." See, non final Office Action, page 8, lines

17-18. Despite that assertion, *Kosbab* does not suggest that the benefits of L-carnitine for skin and lipid metabolism may be enhanced by combination with the other ingredients in the claimed composition. As evidenced by the murine study in the specification, Applicants surprisingly discovered that L-carnitine in combination with the claimed ingredients caused drastic improvement in skin conditions. See, specification, page 14, Table 1. No evidence of this benefit is demonstrated by any part of *Kosbab*.

Similarly, *Murad* fails to disclose the claimed combination of ingredients to be used to treat skin disorders or to stimulate lipid metabolism. The composition in *Murad* is directed to the treatment of connective tissue disorders using a sugar compound, an antioxidant, and amino acid, a transition metal, a moisturizing agent, and a fatty acid. See, *Murad*, Abstract. The disclosed composition in *Murad* does not include L-carnitine or grape seed extract as can be found in the present claims. It also necessarily requires a sugar compound that can be converted to a glycosaminoglycan. See, *Murad*, page 4, paragraph 46. Glycosaminoglycans are essential components of connective tissue. See, *Murad*, page 1, paragraph 3. A person of ordinary skill in the art would therefore not remove an essential component of connective tissue from a composition intended to repair such tissue. They certainly would not replace the sugar compound with L-carnitine, as would be required to reach the present claims.

The composition disclosed by *Murad* also requires a transition metal component to "bind collagen and elastic tissue to rebuild the skin." See, *Murad*, page 5, paragraph 50. The present claims, in contrast, have been shown to treat skin disorders without the addition of either a transition metal component or a sugar compound that can be converted to glycosaminoglycan. There is no indication in *Murad* that such a result would be possible without the sugar or the transition metal. Therefore, there would be no reason for a person of ordinary skill in the art to modify *Murad*, or combine it with the other references directed to treating disorders wholly unrelated to skin, to reach the present claims.

Accordingly, one of ordinary skill in the art would understand that the objectives and anatomical effects resulting from the administration of the compounds of the cited references are entirely distinguishable. As such, one of ordinary skill in the art would have no reason to combine the teachings of *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II*, *Germano*, *Kosbab* and *Murad* to arrive at the present claims with a reasonable expectation of success because the references are directed to different problems in different fields of endeavor.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to combine the teachings of *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II*, *Germano* and *Kosbab* and *Murad* to develop non-invasive treatments for various medical problems because the compositions of the cited references also comprise the natural compounds disclosed in the instant claims. See, non final Office Action, page 7, lines 17-19. However, “[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art.” See, M.P.E.P. §2143.01(III) (2009). Applicants submit that this is not the case with the presently presented claims because the cited references are directed to completely different products having completely different objectives.

Even if some of the components of the compound itself have been shown to have a beneficial effect on skin, the references do not teach that combination as a whole has any effect on skin and the stimulation of lipid metabolism. The composition has been shown to be surprisingly more effective at stimulating lipid metabolism in the skin and treating dermatitis than would have been expected from mere knowledge that some vitamins or amino acids independently may have beneficial effects on skin or lipid metabolism.

Applicants further submit that even if a prima facie case of obviousness has been established, the present claims are not obvious over the cited references because the specification demonstrates unexpected and synergistic results for the claimed combination of ingredients. For example, the specification discloses an experiment in which mice were fed standard Diets A and B consisting of proteins, fat, carbohydrates and cellulose; comparative Diet C consisting of Diet A in addition to vitamin C, vitamin E, grape seed extract and cysteine; Diet D comprising Diet A in addition to L-carnitine, vitamin C, vitamin E, grape seed extract and cysteine; and comparative Diet E consisting of Diet A and L-carnitine. See, specification, page 12, line 24-page 15, line 18.

Table 1 demonstrates that the incidence of dermatitis in the group of mice fed Diet D including both L-carnitine and vitamin C, vitamin E, grape seed extract and cysteine was 0.00, whereas the incidence of dermatitis in the groups fed standard Diets A and B was 0.10 and 0.11, respectively. See, specification, page 14, Table 1. The incidence of dermatitis in the groups of mice fed Diets C or E including either L-carnitine or vitamin C, vitamin E, grape seed extract and cysteine was 0.16. See, specification, page 14, Table 1. Thus, Table 1 demonstrates that a

diet comprising L-carnitine in addition to vitamin C, vitamin E, grape seed extract and cysteine results in a significantly lower incidence of dermatitis compared to diets which do not include the claimed combination. See, specification, page 14, line 1-page 15, line 18; Table 1. As such, the claimed combination of compounds would not have been obvious to one of ordinary skill in the art based on the disclosures of *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II*, *Germano*, *Kosbab* and *Murad*. None of the references disclose the combination of ingredients and none suggest that the combination as a whole would be so surprisingly effective at treating dermatitis and improving skin condition.

For at least the reasons discussed above, the skilled artisan would have no reason to combine the cited references to arrive at the present claims. Moreover, the cited references fail to even recognize the advantages, unexpected benefits and/or properties of compositions and methods for the stimulation of the lipid metabolism in the skin of an animal or a human being for treating dermatitis in accordance with the present claims. As a result, Applicants respectfully submit that independent Claims 1, 4-6 and 18, along with any claims that depend from independent Claims 1, 4-6 and 18, are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the rejection of the pending claims under 35 U.S.C. §103 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly requests an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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